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10/664,861	09/22/2003	Alla V.K. Reddy	AVR-100	4312
24956	7590	02/18/2009	EXAMINER	
MATTINGLY, STANGER, MALUR & BRUNDIDGE, P.C. 1800 DIAGONAL ROAD SUITE 370 ALEXANDRIA, VA 22314			NGUYEN, CAMTU TRAN	
			ART UNIT	PAPER NUMBER
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			02/18/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/664,861	REDDY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Camtu T. Nguyen	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 March 2008.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-5,8,9,12-17,19-21 and 25-35 is/are pending in the application.

4a) Of the above claim(s) 9 and 12-15 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-5,8,16,17,19-21 and 25-35 is/are rejected.

7) Claim(s) 28 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Response to Amendment***

This Office Action is responding to applicant's amendment filed on 3-13-2008. Claims 1-5, 8-9, 12-17, 19-21, 25-33 have been amended. Claims 34 & 35 are newly added.

The Examiner wishes to apologize for the mistaken regarding applicant's election. On this matter, applicant decided to cancel non-elected claims 6-7, 10-11, and 18 in view of their withdrawal as a result of the election.

### ***Response to Arguments***

In claim 1, applicant argued that prior art Boarman condom device does not provide teaching/suggestion, particularly

the contracted configuration for biasing the open end of the condom toward the body of the female user.

In response, applicant has no disclosure support for such limitation. According to paragraph 0011 in the specification, there is support for female condom having a highly elastic resilient pouch portion that is able to freely stretch or extend from an original contracted/compacted configuration into an elongated/stretched configuration, and then return under resilient urging to the original contracted/compacted configuration. Later in the same paragraph, there is support for the pouch made of highly resilient natural latex having high elongation characteristics. Again, no where in the specification is there disclosure support for claimed contracted configuration serving to bias the open end of the condom toward the female anatomy, as recited.

Also in claim 1, applicant argued that prior art Boarman condom device does not teach

the pouch extends when a penis inserted during intercourse,  
and the pouch contracts back to the contracted configuration  
as the penis is withdrawn.

In response, the Boarman reference teaches the female condom (10) tubular body (12) is of latex rubber material (column 3 lines 24-25), of which material is highly resilient. Therefore, it possesses physical properties of stretching and contracting, thus, would be capable of stretching/extending when a penis is inserted, and then springing/contracting back to its contracted/compacted configuration when the penis is withdrawn.

In response to applicant's citation column 4 lines 34-42 of the Boarman reference, such citation from the Boarman reference discloses the application of the condom tubular body (12) inserting into vaginal cavity, prior to the penile insertion therein.

With regards to applicant's arguments directed to claims 9 & 16, specifically to the contracted configuration biasing to contact with the female anatomy, see response to claim 1 above.

With regards to claim 9, in response to applicant's comments specifically directed to the pouch is constructed of highly elastic material such that allows the pouch to elastically extend caused by insertion of the penis into the pouch, the Boarman reference discloses the female condom (10) tubular body (12) is of latex rubber material (column 3 lines 24-25), of which material is highly resilient. Therefore, it possesses physical properties of stretching and contracting, thus, would elastically extend when a penis is inserted, and then would contract back to its contracted/compacted configuration when the penis is withdrawn.

With regards to applicant's arguments to claim 25, specifically, applicant commented that the Boarman's sponge is not positioned in a contracted pouch, such comments are noted but not

persuasive since claim 25 does not require the sponge to be in a contracted pouch. Rather, claim 25 recites the sponge retained in the condom's closed end and being positioned to contact the head of the penis during sexual intercourse.

With regards to applicant's arguments to claim 31, specifically, applicant commented that the Boarman fails to disclose the condom's contracted configuration of average length of a normal vaginal and an elongated configuration of extended to vaginal canal length. In response, claim 31 does not recite a specific length required for the contracted configuration nor for the elongated configuration. It is not unfair and rather within reason in the realm of physical anatomy to comment that the average length of a normal vaginal canal varies from person to person. The Boarman reference, as mentioned above, teaches the female condom (10) tubular body (12) is of latex rubber material (column 3 lines 24-25), of which material is highly resilient. Therefore, it possesses physical properties of stretching and contracting, thus, would stretching/extending up to the length of the vaginal canal when a penis is inserted, and then springing/contracting back to its average length of a normal vaginal canal in its contracted/compacted configuration when the penis is withdrawn.

The Boarman reference is maintained at least for the reasons mentioned above.

With regards to dependent claims 27-28, prior to applicant's disclosure, the Boarman reference illustrates the sponge-like material (40) having a thickness, and the thickness shown in Figures 1-3 appears to be at least 1/2" thick but specifically the sponge-like material (40) could be conceivably be over 2 inches and such thickness is well within reasonable thickness in the art of female condom. Clearly, the sponge thickness of over 2 inches is within routine experimentation range unless applicant would commit to its criticality.

With regards to dependent claims 2, 20, and 30, see response to claim 31.

The claims, as amended, have been carefully considered but deemed not allowable in view of the following rejection(s).

With regards to claim 9 now reciting the pouch of highly elastic material having a structure allowing the pouch to elastically extend caused by penis insertion, such structure suggests the pouch is directed to non-elected Species II (condom with biasing member/strip) instead of elected Species III (condom of highly resilient material). See page 2 of applicant's election response filed on 9-24-2008 and pages 2-3 of restriction/election requirement mailed out 8-22-2007. As such, claim 9 and its dependent claims 12-15 have been withdrawn to non-elected Species II.

#### ***Claim Objections***

Claim 28 is objected to because it recites the sponge is over 2 inches thick but paragraph 0013 supports the sponge made with thickness of  $\frac{1}{2}$  inch to 2 inches. No disclosure support for the sponge over 2 inches thick.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 19, 34, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regards to claims 1 & 3 reciting the contracted configuration serving to bias the pouch's open end & the frame, respectively, toward the anatomy surrounding the vagina for retaining the condom within the vagina, applicant has no disclosure support for such limitation. According to paragraph 0011 in the specification, there is support for female condom having a highly elastic resilient pouch portion that is able to freely stretch or extend from an original contracted/compacted configuration into an elongated/stretched configuration, and then return under resilient urging to the original contracted/compacted configuration. Later in the same paragraph, there is support for the pouch made of highly resilient natural latex having high elongation characteristics. Again, no where in the specification is there disclosure support for claimed contracted configuration serving to bias the open end of the condom toward the female anatomy, as recited.

With regards to claims 19, 34, and 35 reciting the contracted configuration of pouch is less than 3 inches and the extended configuration of pouch is more than 5 inches. Such contracted configuration of pouch is less than 3 inches is not supported by applicant's specification. Accordingly, paragraph 0036 on page 16 supports the invention is constructed with a length of 2 to 3 inches, of which disclosure is not the same as recited in claims 19, 34, and 35.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8, 16-17, 20-21, 25, 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Boarman (U.S. Patent No. 5,113,873). Boarman discloses in Figure 1 a female condom (10) comprising a tubular body (12) having a closed end (30) and an open end (32), the tubular body (12) form of a latex rubber material (column 3 lines 23-26), thus, inherently would display longitudinal biasing means in pouch (16).

With regards to claim 2, 20, and 30, the Boarman tubular body (12) in its contracted configuration is the average length of a normal vaginal canal and its elongated configuration is the full length of the vagina.

With regards to the frame in claims 3, 16, 21, 25, 31, 32, Figure 1 further discloses a shield portion (14) in triangular shape connected to the open end (32). The shield portion (14) is also from of a latex rubber material (column 3 lines 23-26), thus, the shield portion (14) would easily contour concavely on the side that contacts the female anatomy surrounding the vagina.

With regards to retainer/sponge in claims 4, 16, 25, Boarman discloses a sponge-like material (40) retained within cavity (39).

With regards to claims 5, 17, 25, 33, the Boarman sponge-like (40) is compressed upon contact with the head of the penis. Figures 1-3 in the Boarman reference appears to illustrate the sponge-like material (40) is more than 1" thickness.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boarman (U.S. Patent No. 5,113,873). Boarman discloses in Figure 1 a female condom (10) comprising elements as recited in these claims but does not the tubular body (12) in its contracted configuration having a length less than 3 inches. It would have been obvious to one skilled in the art to construct the Boarman female condom (10) tubular body (12) in its contracted/compacted configuration smaller allowing expansion, particularly small enough sized for normal vaginal canal. Of course, it is fair and rather within reason in the realm of physical anatomy to comment that the average length of a normal vaginal canal varies from person to person. As pointed out in applicant's specification in paragraph 0036 that a normal vaginal canal length is 2 to 3 inches. Clearly, therefore, it would have been obvious to one skilled in the art not construct the Boarman's tubular body (12), in its contracted/compacted configuration, larger than normal vagina canal of 2 to 3 inches. For that matter, one of ordinary skilled in the art would have constructed the Boarman's tubular body (12) less than 3 inches, preferably 2 to 3 inches, to be consistent with norm.

Claims 27 & 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boarman (U.S. Patent No. 5,113,873). Boarman discloses in Figure 1 a female condom (10) comprising elements are recited in these claims, particularly, the sponge-like material (40) but does not

suggest its thickness is over 2 inches, as recited. Generally, differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration, temperature, size, or pressure is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (II). However, since the sponge-like material (40) collapses and compresses into much smaller mass upon pressure applied thereto, one skilled would have utilized a sponge-like material of thickness at least over 2 inches as such would maintain the desired length of the tubular body (12) when the sponge-like material (40) collapses.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boarman (U.S. Patent No. 5,113,873) and further in view of Alla et al (U.S. Patent No. 5,992,415). Boarman discloses in Figure 1 a female condom (10) comprising elements are recited in these claims, particularly, the sponge-like material (40) but does not suggest it including an insertion opening, as recited. Alla et al discloses in Figure 3 a female condom (10) comprising a sponge (28) retained at the closed end thereof, the middle portion of the sponge (28) is concave (32) or bowl-like (column 3 lines 14-20). Therefore, one skilled in the art would have been motivated to modify the Boarman’s sponge-like material (40) to have it centered concave or bowl-like, suggested by Alla et al, as such would facilitate proper insertion by the user's finger or tool within the condom device.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boarman (U.S. Patent No. 5,113,873) and further in view of Valentine et al (U.S. Patent No. 5,387,206).

Boarman discloses in Figure 1 a female condom (10) comprising elements are recited in these claims, particularly, the sponge-like material (40) but does not suggest it including notches. Valentine et al discloses in Figures 2 & 3 a medical sponge (10) comprising notches opposting notches (24). Therefore it would have been obvious to one skilled in the art modify the Boarman's spong-like material (40) to include notches, as taught by Valentine et al references, as such would provide folding or bending of the sponge-like material (40), thereby, facilitating smoother insertion.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/  
Examiner, Art Unit 3772

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772